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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/624,395	07/24/00	NERIISHI	000000

HM12/0814  
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EXAMINER
FORNAN, D

ART UNIT	PAPER NUMBER
1000	

DATE MAILED: 08/14/01 *ef*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/624,395

Applicant(s)

NERIISHI, KEIKO

Examiner

BJ Forman

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-4 are each indefinite in the recitation "multiple kinds of biomolecules" because it is unclear whether each array comprises more than one kind of "biomolecule" e.g. proteins and nucleic acids and etc. It is suggested that the claims be amended to clarify e.g. replace "kinds of biomolecules" with "sequences of oligonucleotide" (specification, page 11, lines 3-8)

b. Claims 5-6 are each indefinite in the recitation "multiple kinds of detecting bodies" because it is unclear whether each array comprises more than one kind of "detecting body" e.g. labels, proteins and nucleic acids and etc. It is suggested that the claims be amended to clarify e.g. replace "kinds of biomolecules" with "labeled sequences of oligonucleotide" (specification, page 11, lines 3-8).

c. Claims 1-6 are indefinite in the recitation "the biomolecules are arrayed and fixed on the stimuable phosphor sheet" because it is unclear whether the biomolecules physically contact the phosphor sheet or are merely "arrayed and fixed" on some surface above the phosphor sheet. It is suggested that the claims be amended to clarify e.g. "wherein the biomolecules are fixed by covalent bonding to the poly-L-lysine coated phosphor sheet" (specification, page 14, lines 6-9).

d. Claim 4 is indefinite because the claim is drawn to a method for analyzing a biomolecule but the method does not recite any methods steps of analyzing the biomolecule. It

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is suggested that the claim be amended to recite positive and active steps of analyzing e.g. "comparing detected signal to previously stored information to thereby analyze biomolecule" (specification, page 15-21).

e. Claim 4 is indefinite in the recitation "causing the stimutable phosphor sheet to store energy" because "causing" is a non-descriptive activity and therefore is it unclear how the sheet stores energy. It is suggested that the claim be amended to clarify e.g. replace "causing" with "exposing the phosphor sheet to visible light and placing in a dark place to thereby cause" (specification, page 15, lines 11-17).

f. Claim 6 is indefinite because the claim is drawn to a method for analyzing a sample but the method does not recite any methods steps of sample analysis. It is suggested that the claim be amended to recite positive and active steps of analyzing e.g. "comparing detected signal to previously stored information to thereby analyze the sample" (specification, page 15-21).

g. Claim 6 is indefinite in the recitation "causing the stimutable phosphor sheet to store energy" because "causing" is a non-descriptive activity and therefore is it unclear how the sheet stores energy. It is suggested that the claim be amended to clarify e.g. replace "causing" with "exposing the phosphor sheet to visible light and place in a dark place to thereby cause" (specification, page 15, lines 11-17).

h. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the polyester substrate, phosphor layer comprising a binder and BaFX phosphor particles and protective layer (specification, page 13, lines 18-25). The omitted elements are essential elements in the claimed microarray of arrayed and fixed biomolecules because without the omitted elements, the claims do not distinctly describe the invention.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986). The claims are drawn to a microarray comprising a stimutable phosphor sheet and multiple kinds of biomolecules arrayed and fixed on the phosphor sheet. The claims are given the broadest reasonable interpretation consistent with the indefinite claim language wherein, as stated above, it is unclear how the biomolecules are arrayed and fixed and the specification wherein the microarray “has broad meanings embracing.... a macroarray” (page 1, lines 14-16).

Regarding Claim 1, Shiraishi et al. disclose a microarray comprising a stimutable phosphor sheet, and multiple kinds of biomolecules arrayed and fixed on the stimutable phosphor sheet (Column 5, lines 53-65 and Column 13, lines 26-35).

Regarding Claim 2, Shiraishi et al. disclose the microarray wherein the multiple kinds of biomolecules are fixed on or within a protective layer of the stimutable phosphor sheet (Column 12, line 67-Column 13, line 10).

Regarding Claim 3, Shiraishi et al. disclose the microarray wherein the multiple kinds of biomolecules are fixed on or within a phosphor layer of the stimutable phosphor sheet (Column 5, lines 53-65 and Claim 5).

Regarding Claim 5, Shiraishi et al. disclose a microarray comprising a stimutable phosphor sheet, and multiple kinds of detecting bodies arrayed and fixed on the stimutable phosphor sheet (Column 5, lines 53-65 and Column 13, lines 26-35).

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***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiraishi et al. (U.S. Patent No. 4,617,468, issued 14 October 1986) in view of Davis et al. (Basic Methods in Molecular Biology, "DNA Hybridization", 1986, pages 84-87).

Regarding Claims 4 and 6, Shiraishi et al. teach a method for analyzing a biomolecule (Claim 4) and a sample (Claim 6) comprising: preparing a microarray which comprises multiple kinds of biomolecules (Claim 4) and detecting bodies (Claim 6) (i.e. labeled molecules e.g. proteins and nucleic acids) arrayed and fixed on the stimuable phosphor sheet; causing the stimuable phosphor sheet to store energy from the energy generating substance with which the fixed biomolecule is labeled; exposing the stimuable phosphor sheet to stimulating rays which cause the phosphor sheet to emit light in proportion to the amount of energy stored thereon and photoelectrically detecting the emitted light to detect the labeled biomolecule (Column 13, line 41-Column 14, line 5 and Column 14, line 49-Column 15, line 32). Shiraishi et al. teach the biomolecule is labeled and they teach providing the label by known methods (Column 13, lines 26-40) but they do not specifically teach labeling the fixed biomolecule by hybridization with a labeled biomolecule. However, labeling a biomolecule by hybridization with a labeled biomolecule was well known in the art at the time the claimed invention was made as taught by Davis et al. Specifically, Davis et al. teach hybridizing a labeled biomolecule with a biomolecule fixed on a support (page 85). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the labeling of Shiraishi et

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al. wherein all of the arrayed and fixed biomolecules are radioactively labeled with the labeling taught by Davis et al. wherein only biomolecular probes are labeled and wherein the labeled probes hybridize to specific arrayed biomolecules to thereby detect only specific biomolecule(s) and based on the known hazards of radioactive labels, label biomolecular-specific probes and hybridizing the probes to the arrayed biomolecules thereby reducing the number of radio-labeled biomolecules and reducing non-specific detection for the expected benefit of reduced biohazard risk and increased biomolecule-specific detection.


### Conclusion

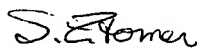
7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
August 13, 2001

  
S. E. Forman  
Supervisor to the Examiner  
Patent Office